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09/966,441	09/28/2001	Christopher E. Szymczak	MCP-284	5360

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EXAMINER

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 05/30/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/966,441

Applicant(s)

SZYMCAK ET AL.

Examiner

Brian S Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-28 is/are pending in the application.
- 4a) Of the above claim(s) 6, 18, 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-14, 16, 17 and 19-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Summary of Action

- I. The objection of specification will not be maintained in light of the amendment.
- II. The objection of claims 1-3, 5, 14-15, 17 and 26 will not be maintained in light of the amendment.
- III. The rejection of claims 1-2, 4-5, 7-8 and 11-12 under 35 USC 102(b) will be maintained for the reason of the record.
- IV. The rejection of claims 3, 9-10, 13-14, 16-17 and 19-26 under 35 USC 103(a) will be maintained for the reason of the record.
- V. The newly added disclosure is objected to under 35 USC 132, as being containing new matter.
- VI. Claims 1, 1-5, 7-12, 14 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Status of Application

1. By amendment filed February 6, 2003, Claim 15 has been cancelled and Claims 1-3, 5, 9, 14, 17, 23-24 and 26 have been amended. Claims 1-5, 7-14, 16-17 and 19-26 are currently pending.

Applicants Response to Restriction Requirement

2. Although applicants (Timothy E. Tracy) made a provisional election with famotidine as the elected species on September 20, 2002 during a telephonic conversation, applicants do not

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wish to make such affirmation (Remarks-Restriction Requirement at page 5). Instead, applicants desired to elect loperamide as the elected species.

Applicants originally have received an action on the merits for the provisionally elected species, namely famotidine. However, Applicants effort to shift to claiming another species after the election was made is considered improper response. Therefore, it is still proper to withdraw claims 6 and 18 as being drawn to a non-elected invention.

It is noted to applicants that when the allowance of a generic claim or the elected species, applicants will be entitled to consideration of claims to addition species (by the Examiner's choice) which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

Response to Amendment

3. The amendment filed February 6, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the weight ratios of simethicone to adsorbent or the weight ratios of simethicone to total adsorbent , "at least about 0.45", "at least about 0.5", "at least about 0.56" or at least "about 0.57" are not supported by the original disclosure.

The original specification (abstract; the summary of the invention; paragraph 32) discloses that the weight ratio of simethicone to adsorbent or total adsorbent is "at least about 1:2.22"; "at least about 1:2.00"; "a least about 1:1.80"; and "at least about 1 part simethicone to 1.75 parts adsorbent". It is understood in view of the original specification that "at least about

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1:2.22” relates to the range of the weight ratio of simethicone to adsorbent, for example 1:2.20, 1:2.21, 1:2.22, 1:2.23, 1:2.24, 1:2.25, 1:2.26, 1:2.27, 1:2.28, 1:2.29, 1:2.30, etc... (their corresponding quotients are 0.455, 0.452, 0.45, 0.448, 0.446, 0.444, 0.440, 0.438, 0.437, 0.435, etc...). “at least about 1:2.22” limits that the lower range of the claimed ratio must be no less than about 1:2.22 (e.g., 1:2.20, 1:2.21) while the higher range of the claimed ratio can be any ratio which is greater than 1:2.22. As seen above, when the ratio increases, the corresponding quotient decreases. However, applicants amendment “at least about 0.45”, which reads on the range of 0.40, 0.41, 0.42, 0.43, 0.44, 0.45, 0.46, 0.47, 0.48, 0.49, etc..., contradicts the original disclosure. For example, the quotient 0.9 reads on “at least about 0.45”. However, its conversion to ratio (1:1.111) does not fall within “at least 1:2.22”, nor “at least about 1:1.80”, nor “at least about 1 part simethicone to 1.75 parts adsorbent”. Although some ranges of the ratio in newly amended disclosure “at least about 0.45” overlap with the claimed range in the original disclosure, some lie outside of the originally claimed range disclosed in the originally filed application. Therefore, the Examiner considers that amendment filed February 06, 2003 introduces new matter into the disclosure of the invention.

Similar logical reasoning also applies to “at least about 0.5”, “at least about 0.56” and at least “about 0.57”.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 1-5, 7-12, 14 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The reasoning of this rejection has been discussed in above new matter objection under 35 USC 132.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevens et al. (US 5679376 A).

This rejection is analogous to the original rejection.

6. Claims 1-2, 4-5, 7-8 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Lubber et al. (US 6103260 A).

This rejection is analogous to the original rejection.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 3, 9-10, 13-14 and 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitsusho Yakuhin Kogyo KK (JP 398241) in view of Tobyn et al. (International Journal of Pharmaceutics 169 (1998) 183-194).

This rejection is analogous to the original rejection.

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8. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitsusho Yakuhin Kogyo KK (JP 398241) in view of Tobyn et al. (International Journal of Pharmaceutics 169 (1998) 183-194) and Stevens et al. (US 5679376).

This rejection is analogous to the original rejection.

Response to Arguments

9. Applicant's arguments filed February 6, 2003 have been fully considered but they are not persuasive.

Applicant's argument takes position that there is no teaching or suggestion of the claimed ratio of simethicone to adsorbent. Applicant alleges that the ratio of simethicone to adsorbent (dibasic calcium phosphate+microcrystalline cellulose+ colloidal silicon dioxide) in Stevens is 125:667, which is about 0.19 and the referenced ratio of about 0.19 does not fall within the claimed ratio of at least about 0.45.

Unlike applicant's argument above, the claimed scope of "an adsorbent" includes not only mixtures of dibasic calcium phosphate, microcrystalline cellulose and colloidal silicon dioxide, but also dibasic calcium phosphate, microcrystalline cellulose or colloidal silicon dioxide alone or any two combinations selected from dibasic calcium phosphate, microcrystalline cellulose and colloidal silicon dioxide. Therefore, the referenced ratio of 1:2.12 or about 0.47 (simethicone to microcrystalline cellulose) or 1:2.37 or 0.42 (simethicone to the combination of microcrystalline cellulose and colloidal silicon dioxide) anticipates the claimed invention.

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Applicants argument takes position that Lubers disclosed ratios of simethicone to granular tricalcium phosphate, 0.28 (1:3.5) in Examples 1-2 and 0.25 (1:4) in Example 6 do not fall within the claimed ratio of at least about 0.45. This argument is not persuasive. As discussed in above new matter rejection, the newly added materials do not support the original disclosure. Therefore, the referenced ratios anticipate the claimed invention.

Applicants allege that the Examiner's rejection of claims 4-5, 7-8 and 11-12 in view Stevens (OA at 7-8) is improper and should be withdrawn. This argument is not persuasive. Applicants are correct that the Examiner made an inadvertent error in referring Stevens instead of Luber. However, the Examiner does not believe that such error leads to the misinterpretation of the rejection because the whole context of the rejection properly addressed the reasoning of the rejection with the correct identification of the specific teaching from Luber (the Examiner's reference to claims 7-8, column 5, lines 18-21 and Examples 4-6 in OA at 7-8). With the heading of claim rejection as being anticipated by Luber et al. (OA at 6), it would have been apparent to applicants or readers that the whole context of the rejection is in view of Luber. It is noted that the Examiner's reference to Stevens should be corrected as Luber (OA at 7-8).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

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In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600

A handwritten signature in black ink, appearing to read 'Zohreh Fay', is written over the printed name.